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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,993	04/17/2000	MARIE-PAULE KIENY	017753-122	5746

7590 07/16/2003

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Application N .	Applicant(s)	
09/462,993	Kieny, Marie-Paule	
Examiner	**Art Unit**	
Q. Janice Li	1632	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed on 2/12/03 has been entered as Paper #24. Claims 44, 46, 47, 50, 56, 58, 69, and 71 have been amended, claims 73-82 are newly added. Claims 44-82 are pending in the application, and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in paper #24 would be addressed to the extent that they apply to the current rejection.

Claim Objections

Claim 44 is objected to because the newly added phrase "if the natural polypeptide lacks a secretory sequence, inserting a secretory sequence" fails to further limit the claimed subject matter. Applicants are reminded that the scope of the amended claim 44 is limited to HPV E6 and E7 derivatives, which is known to lack a secretory sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

WRITTEN DESCRIPTION REQUIREMENT

Claims 44-72 stand rejected and claims 73-82 are newly under 35 U.S.C. 112, first paragraph, for reasons of record and following.

With regard to the homologues of the HPV E6 and E7, applicants submitted seven references to illustrate that a number of type-specific and cross-reactive epitopes of the E6 and E7 regions of HPV were known at the time the application was filed.

The references and the argument have been fully considered but they are not persuasive. This is because these references teach that the antigeneicity of derivatives of the E6 and E7 polypeptides is closely related to the HLA-binding affinity (e.g. Ressing et al), and located at the N-terminal region (e.g. Stacey et al, Selvey et al, and Tindle et al). Seven of the eight references teach only *HPV 16*, whereas the instant claims drawn to *any* type of HPV. *None* of the eight references discusses the sequence homology and antigeneicity of HPV derivatives. In fact, *Stacey et al* teach, "THE PUTATIVE ZINC FINGER DOMAINS WERE CONSISTENTLY NON-REACTIVE, DESPITE COMPUTER PREDICTIONS OF RELATIVELY HIGH ANTIGENEICITY". In light of these teachings and considerations, the specification fails to provide an adequate written description for the claimed genus of homologues of *immunogenic* derivatives of HPV E6 and E7.

With regard to the non-oncogenic variants, in paper #24, applicants argue that the specification teaches non-oncogenic variants by reference to the prior art of record, Munger et al, Phelps et al, Crook et al, and Heck et al, therefore provides adequate written description.

The argument and references have been fully considered but found not persuasive. This is because although the cited references do teach the oncogene-

binding region and compare the structural characteristics of certain low risk and high-risk HPV strains concerning oncogenecity, they do not teach the non-oncogenic variants. There is no general teaching for a consensus structure that define *non-oncogeneic variants*. Further, it is noted that the only thoroughly studied oncogenic strain discussed in these references is HPV16, whereas the claims encompass any of the many strains of HPV. Moreover, *Crook et al* teach that the oncogene-binding region is associated with the N-terminal sequences. Accordingly, if the non-oncogenic variants lack the N-terminal sequences, then the resulting peptide would loss the required immunogenecity. In light of these teachings and considerations, the specification fails to provide an adequate written description for the claimed genus of non-oncogenic variants of immunogenic derivatives of E6 and E7 of HPV.

It is noted that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). 35 U.S.C. § 112 requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In re Fisher, 166 USPQ 18, 24 (CCPA 1970).

Applicants are reminded that the Federal Circuit has stated that:

> a specification need not disclose what is well known in the art. See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). however, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, **when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out,**

> **undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.** It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.
> Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997) (emphasis added).

Therefore, for reasons of record and those set forth foregoing, the specification fails to meet the statutory enablement requirement under 35 U.S.C. first paragraph.

ENABLEMENT REQUIREMENT

To the extent that the claimed homologues and non-oncogeneic variants of HPV E6 and E7 are not adequately described in the instant disclosure, claims 44-72 stand rejected and claims 73-82 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been adequately described.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "the natural polypeptide". There is insufficient antecedent basis for this limitation in the claim.

Claim 45 depends from claim 44 and recites the limitation "said polypeptide". However, claim 44 recites "immunogenic polypeptide" (line 3), and "natural polypeptide" (line 5), and "a polypeptide" (line 8). It is unclear which polypeptide the claim refers to, thus, the metes and bounds of the claim is uncertain.

Claim 51 recites the limitation "said compound". There is insufficient antecedent basis for this limitation in the claim.

Claim 73 recites the limitation, "the sequence encoding at least one immunogenic polypeptide".

Claim 73 is vague and indefinite because it define a promoter as "the 7.5k promoter", it is unclear whether this refers to a particular promoter or any promoter having 7.5k size of nucleic acid base pairs, thus, the metes and bounds of the claim are uncertain.

Claim 80 is vague and indefinite because the meaning of the phrase "a method for the treatment of an HPV-related cancerous or precancerous condition is a subject" could not be determined in the context of the claim, thus the metes and bounds of the claim are unclear.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Application/Control Number: 09/462,993
Art Unit: 1632

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
July 14, 2003

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER